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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/359,260	07/22/1999	ROBERT L. CAMPBELL	P3250	2590

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EXAMINER	
WESSENDORF, TERESA D	
ART UNIT	PAPER NUMBER
1639	24

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/359,260	CAMPBELL ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this c mmunication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *74 and 76-95* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *74 and 76-95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Claims

Claims 74 and 76-95 are pending and under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 74 and 76-95 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The claimed method of identifying an activity of a peptide that satisfies a test requirement lacks a specific or practical utility. The specification provides nothing more than exploratory studies or theories. It does not describe a single peptide that has been identified with a specific utility. The specification does not disclose the kind of activity e.g., biological, chemical, physical, biochemical role or significance of the peptide obtained from undefined library. The specification, page 72, abstract states that the method finds use in the methods of drug discovery, identifying components of culture medium, and identifying and/or designing peptides with particular pharmacological or therapeutics activities. However, an intended use is not equivalent to a specific use required by

the statute. Thus, only after further research and further experiments would it seem that a specific and substantial credible utility might be found for the claimed peptide activity. This further characterization, however, is part of the act of invention and until it has been undertaken, applicants' claimed invention is incomplete.

The court in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that:
The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . a patent is not a hunting license. . . .[i]t is not a reward for the search, but compensation for its successful conclusion.

Thus, there was no immediately apparent or "real world" utility as of the filing date.

In order for the method using a library to be useful, as asserted, for diagnosis of a disease, let alone a therapeutic activity, there must be a well-established or disclosed correlation or relationship between the claimed library and a disease or disorder. "Congress intended that no patent be

granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101. The evidence of record is inadequate to determine the peptide activity or utility, disease(s), drug(s) for which the peptide with a discover activity would be useful. In *Brenner*, the Court approved a rejection for failure to disclose any utility for a compound where the compound was undergoing screening for possible compounds the utility of which has also not been identified. *Brenner*, 148 USPQ at 690. Here, there is no evidence that the claimed isolated peptides have any utility. *See In re Kirk*, 153 USPQ 48, 53 (CCPA 1967) (quoting the Board of Patent Appeals, 'We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of ***guessing game*** that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.')

Claims 74 and 76-95 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 74 and 76-95 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The disclosure fails to provide an adequate written description of the claimed method of identifying a peptide with an activity that satisfies a test requirement comprising selecting a first test peptides library using a space-filling

design. The specification is full of generalized statements and provides definitions that are not very descriptive of the terms or art-recognized. For example, the specification, page 6, last incomplete paragraph, recites a relationship (e.g., mathematical relationship) is determined between at least one parameter or descriptor (e.g., physical, chemical, biological and/or topological parameters) of the test compounds from within the first test library which are included in the plurality of first culture media and the measured indicia of the property. The relationship can be used as a predictor to identify ***additional lead compounds*** as components of culture media that are expected, based on their parameters. To give indicia of the measured property that satisfy a test requirement. It does not describe in detail the different physical, chemical, biological or topological parameters, either singly or in multiples, included in each of the broad descriptors. The term activity, alone, is used to mean all functions that peptides can exhibits. The specification provides nothing more than theoretical determination of a peptide activity. The methodologies are exploration by trial and error to find a peptide having a desired activity, if any. See further the disclosure at page 10, lines 29- 30, which states, "the test compound library will be representative of the compound space. In many instances, a

compound space of interest may be so vast that it is computationally difficult to determine a test library therefrom…."

Based on the numerous and little known statements provided in the specification, it would be difficult to determine the applicability of the method to any activity of any peptide. Thus, the trial and error e.g., exploratory studies do not provide an adequate description of the claimed invention.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 74 and 76-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claims 74 and 76-95 are so obscure it is not clear as to what is the intended to be claimed. This is made more ambiguous for using terminologies that do not conform with the accepted meaning in the art. For example: "space-filling design"; "indicia of peptide activity"; "whole molecule parameter"; "sequence-specific parameter"; "test requirement"

and so forth. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). Claim 74 is indefinite, as there appear to be a lack of nexus of the method steps. It does not clearly set forth the test requirement that has to be satisfied to find an activity for the peptide. It is not clear, within the context of the claims, how an activity of a peptide can be determined from a peptide library of undefined components. The arbitrary designation of "first" and "second" test peptides is indefinite as to the differentiating characteristics of each of these arbitrary designations with respect to structure etc. Further, it is not clear, within the context of the claim what constitutes a "test" peptides. "Selecting" is not a positive, active, manipulative process step and unclear as to the basis of said selection. "Measuring an indicia of said activity" is indefinite as to what constitutes indicia, in the context of the claim. The metes and bounds of the "test requirement", "test peptides library" "space-filling design", "peptide activity"; "indicia of activity"; "plurality of first test peptides"; "whole molecule parameter" and

"sequence-specific parameter" are not clearly set forth. Each of these terms covers infinite variables that do not circumscribe the claim with particularity, as required by the statute.

B). Claim 76 is unclear as to the kind of relationship determined using the recited formula. Furthermore, it is not clear whether a whole molecule parameter refers to the number of molecules or property of a molecule, in the context of the claim.

C). Claims 77 and 78 lack antecedent or broaden the base claim. The base claim does not recite for a quantifying or qualifying range of an indicia activity. Is identifying different from qualifying?

D). Claim 79 is indefinite as to what constitutes a "non-parametric regression formula" within the context of the claim.

E). Claim 80 lacks antecedent support and broaden the base claim 1. The base claim does not recite for an estimating step of the indicia of the activity with the conditional (if) limitation.

F). Claim 81 is indefinite as to the recited "global characteristics" especially since the base claim does not recite for said characteristics. Also, "respective candidate peptide" is not positively recited in the base claim. Is this the test peptide? The use of different terminologies to mean the same thing provides for confusion.

G). Claims 82-86 fail to ascertain the claimed invention with precision. The metes and bounds of the different terms e.g., total charge are not clearly set forth by the claims or specification.

H). The terms ""enhancement" or "inducement" " in claim 88 or claim 93 and "inhibition" in claim 89 or claim 92 are relative terms which render the claim indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

I). Claim 91 is unclear as to whether any of the intended biological activity of enhancement or inhibition is accomplished using the same method, especially in the lack of positive showing in the specification. A plurality of culture media is not positively recited in the base claim 90 or 76.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 74, 81, 87-90 and 94 are rejected under 35 U.S.C. 102(b) as being anticipated by Tenson et al for reasons of record.

Response to Arguments

Applicants admit that Tenson et al teaches two random peptide libraries of the form M(X)20 and M(X)4. But argue that this random selection approach does not create a subset of representative candidates that is representative of all of the respective spaces. The 5-condon(codon) library of Tenson which contains a collection of pentapeptides all having Met at the N-terminus, covers only a particular region of pentamer space. It is further argued that the 21-codon library contains only Met at the N-terminus, regardless of the peptide length. The peptides in this library also will not be representative of all peptide space. Both the first and second libraries of Tenson were constructed to contain Met at the N-position, and thus do not constitute a space filing design as set forth in the claim. In response, the claims do not recite for any peptide sequence or for any space-filling design. Furthermore, Tenson's 21-codon library identifies the peptide length of about 10 amino acids. The broadly claimed peptide does not recite for any peptide sequence only its length. Therefore, the method of Tenson, which

uses specific peptides, that fills a pentamer space, albeit, not perhaps, representative of peptide space, as argued, anticipates the claimed invention.

Claims 74, 92, 94, 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Ostrem for reasons advanced in the last Office action.

Response to Arguments

Applicants admit that all of the peptides in the first library of Ostrem are eight amino acids long. But argue this is a constant value, and is not a sequence independent parameter. The first library of Ostrem is argued to be all of octapeptide space generated by combinatorial chemistry. It represents the complete octamer universe and does not constitute a space filling design representative of the space as claimed. Applicants admit that Ostrem teaches that a number of different secondary library was generated (page 1056, col. 1., paragraph 1). It is further admitted that a handful of modification of this library were described and two peptides were mentioned. These examples are argued not to represent a space filling design. In reply, the claims do not recite the extent of a space filling design requirement. This is especially so, as the claims recite for any type of peptide. Thus, applicants' admission that Ostrem discloses handful modifications of the specific peptide anticipates the broad claimed peptide of undefined variables.

No claim is allowed.

CHANGE OF EXAMINER

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
July 14, 2003